

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)
)
)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8465

Bartle, C.J.

April 26, 2010

Sandi J. Hanson ("Ms. Hanson" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Mark M. Hanson, Ms. Hanson's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Azam Ansari, M.D. Dr. Ansari is no stranger to this litigation. According to the Trust, Dr. Ansari has signed in excess of 160 Green Forms on behalf of claimants seeking Matrix Benefits. See Pretrial Order ("PTO") No. 8445 (Mar. 31, 2010). Based on an echocardiogram dated May 20, 2002, Dr. Ansari attested in Part II of Ms. Hanson's Green Form that she suffered from moderate mitral

3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$597,201.⁵

In the report of claimant's echocardiogram, Dr. Ansari stated that Ms. Hanson had "moderate mitral regurgitation, which occupied 21% of the left atrial volume." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2005, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Parmar concluded that there was no reasonable medical basis for Dr. Ansari's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Parmar explained that:

4. Dr. Ansari also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's findings of an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

The [mitral regurgitation] is mild by Singh criteria. The echo technician has clearly over-estimated the [mitral regurgitant area] by inclusion of low velocity flow. The real time echo images reveal only mild [mitral regurgitation] but there is suddenly a still frame in the tape which is supposedly [mitral regurgitation]. In my opinion this still frame does not appear to be all related to [mitral regurgitation]. This frame includes low velocity flow. This mis-assessment has erroneously given an elevated [mitral regurgitant area]/LAA ratio. My calculation shows mild [mitral regurgitation] by Singh criteria (by my assessment the [mitral regurgitant area]/LAA ratio is 13%).

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Hanson's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that the auditing cardiologist's determination as to claimant's level of mitral regurgitation was unreasonable because it is inconsistent with the findings on Ms. Hanson's echocardiogram report, which was performed by a cardiologist who

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Hanson's claim.

participated in the Trust's Screening Program.⁷ Claimant further argued that "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."⁸ Finally, claimant contended that the Trust was not properly applying the reasonable medical basis standard established in the Settlement Agreement and that the auditing cardiologist simply substituted his own opinion for that of the attesting physician.⁹

The Trust then issued a final post-audit determination again denying Ms. Hanson's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Hanson's claim should be paid. On March 20, 2006, we issued an Order to show cause and referred the

7. See Settlement Agreement § IV.A.1 (Screening Program established under the Settlement Agreement).

8. In support of this argument, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, specifically addressed Ms. Hanson's echocardiogram.

9. Claimant also contended that the Trust should ensure that the auditing cardiologists do not have any "biases" against claimants. As there is no evidence that the auditing cardiologist had a "bias", this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how these filings entitle her to Matrix Benefits, they are not pertinent to the disposition of this show cause claim.

matter to the Special Master for further proceedings. See PTO No. 6077 (Mar. 20, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 16, 2006, and claimant submitted a sur-reply on July 13, 2006. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Hanson reasserts the arguments that she made in contest. In addition, claimant suggests that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of mitral regurgitation. According to claimant, "[n]either diagnosis is

correct or incorrect; both fall within the realm of having a 'reasonable medical basis.'"

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. The Trust also argues that claimant failed to establish a reasonable medical basis for her claim because claimant did not rebut any of Dr. Parmar's specific findings. Moreover, the Trust asserts that Dr. Parmar evaluated claimant's level of mitral regurgitation as required by the Settlement Agreement and determined that the planimetered jet improperly included low velocity flow, which "increased the percentage of the atrium covered by mitral regurgitation." Finally, the Trust contends that claimant can neither rely on a single frame to support an assertion of moderate mitral regurgitation nor can she rely on the fact that an echocardiogram was performed through the Screening Program to support a claim for Matrix Benefits.¹⁰

In her sur-reply, claimant reasserts her argument that the measure of mitral regurgitation is subjective and that the

10. In its Reply, the Trust also submitted an excerpt of an analysis by Dr. Joseph Kisslo, which was originally included as part of the Trust's Response in Opposition to Carey & Danis Claimants' Cross Motion for a Change in the Burden of Proof in the Show Cause Process and Other Relief, filed by the Trust on November 28, 2005. As the show cause process should be limited to the specific show cause record at issue (which should not simply include isolated references to other filings in MDL 1203), and the excerpted analysis is unnecessary to the resolution of this claim, the court will not consider this excerpt. Claimant's argument in her sur-reply that Dr. Kisslo's findings contradict those of the auditing cardiologist is likewise irrelevant to the resolution of this claim.

auditing cardiologist's difference of opinion does not disprove the existence of a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest the finding of Dr. Parmar that claimant had only mild mitral regurgitation due to deficiencies made by the attesting physician. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Hanson rests only on Dr. Ansari's check-the-box diagnosis on her Green Form and Dr. Ansari's echocardiogram report. She does not refute or respond to Dr. Parmar's finding that her echocardiogram did not establish moderate mitral regurgitation due to the improper inclusion of low velocity flow and the reliance on a single still frame that did not reflect moderate mitral regurgitation. Claimant also never identified any particular error in Dr. Parmar's measurements or conclusions. Mere disagreement with the auditing cardiologist without identifying and substantiating any specific errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof. Stated differently, a claimant cannot request that the court simply disregard the findings of the auditing cardiologist in favor of the original conclusions of the attesting physician. Thus, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. Dr. Parmar determined in audit, and Ms. Hanson does not adequately dispute, that her attesting physician incorrectly characterized low velocity flow as mitral regurgitation, resulting in an erroneous diagnosis of moderate mitral regurgitation. Contrary to claimant's argument, Dr. Parmar properly applied the reasonable medical basis standard established under the Settlement Agreement. We previously have concluded that low velocity flow is not properly considered mitral regurgitation. In PTO No. 2640, we explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow," and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Parmar concluded that "[t]he

echo technician has clearly over-estimated the [mitral regurgitatnt area] by inclusion of low velocity flow.... This mis-assessment has erroneously given an elevated [mitral regurgitant area]/LAA ratio." Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.¹¹

This is particularly true in the context of Ms. Hanson's claim where she seeks to recover Matrix Benefits based on a single measurement of regurgitation on her echocardiogram. For a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram.¹² To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

Moreover, we have stated previously that "'[o]nly after reviewing

11. Similarly, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Parmar merely substituted his opinion for that of the attesting physician. Instead, Dr. Parmar found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Neither claimant nor claimant's attesting physician, however, adequately refuted or responded to this determination.

12. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on an isolated instance of what appears to be the requisite level of regurgitation to meet this definition.

multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate regurgitation has been achieved." PTO No. 6897 (Jan. 26, 2007) (quoting PTO No. 2640 at 9). Claimant has not established that the single measurement offered in support of her claim is representative of her level of mitral regurgitation. On this basis as well, claimant has failed to establish a reasonable medical basis for her claim.

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of her claim for Matrix Benefits was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive for an echocardiogram performed in the Screening Program is a limited amount of medical services or cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Hanson's claim for Matrix Benefits and the related derivative claim submitted by her spouse.